

REMARKS

Claims 1 and 3 have been amended. No new matter has been amended.

Reconsideration of claims 1-19 and 21-24 is respectfully requested. Claim 20 was previously cancelled.

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the folded portion, recited in claims 5 & 6 and as described in the specification on page 8 lines 9 & 17.

The sleeve 708 as shown in Fig. 7 is located in between 401 and 401A. The end of the stocking 404 is folded over on itself as shown in Figs. 10 and 12 and as claimed in claims 5 and 6. Figs. 10 and 13 shows end of the stocking folded over on itself with 404 and 403 marking the ends of the sleeve.

Claims 1-6, 9-19, and 21-24 are rejected under 35 U.S.C. 103 as being unpatentable over Gold (U.S. Patent No. 5, 187, 814) and further in view of Sabin et al (U.S. Patent No. 5,984,953).

Gold discloses a heated garment for heating a body part. A pocket assembly is fixed to the garment for receiving the heater pack in a fixed location.

Sabin discloses a self-heating, disposable heating pack. The heat pack stiffens after being activated to release heat when in use.

Claims 1-6, 8-19, and 21-24 disclose structure that is different and not found in Gold or Gold in view of Sabin. The invention of the instant application claims a

moldable gel pad. Both references teach “a pack”, a heat pack is not a moldable gel pad. As a result, the invention of the instant application is not made obvious, by Gold in view of Sabin, and claims 1-6, 8-19, and 21-24 are patentable.

Further, applicant strongly disagrees with the Examiner’s statement on page 4, line 13. The Examiner states that:” The Gold device would be capable of performing the method of treating a patient having venous insufficient [sic] via Gold’s sock using Sabin et al’s gel pack. “ It would not be possible to use Gold’s sock with Sabin et al’s gel pack to treat a patient having venous insufficiency. Sabin’s heat pack is not the same as a gel pad. The application of pressure in the instant invention is different from the use of heat in the references. **In particular, it is commonly known for those skilled in the art to avoid any application of heat to an area suffering from venous insufficiency. Heat is known to dilate veins. In some cases, some doctors instruct their patients to avoid all forms of heat including a stove or sources of heat like a fireplace. Even showering is avoided at high temperatures. There would be no reason a person of ordinary skill in the art would look to provide heat to treat venous insufficiency. This is particularly relevant to the propriety of combining the references as suggested by the Examiner.**

In the Postgraduate Medicine article entitled “ Successful Methods of Treating Leg Ulcers” by Tania Phillips, MD, Vol. 105, No.5, May 1, 1999, heat packs should be avoided for treating leg ulcers. Specifically, this article states:” ...direct contact with heat

should be avoided because of the risk of thermal injury.” The article is attached hereto as Exhibit “A”. Further, compression with heat also should be avoided, as the compression would greatly increase the likelihood of severe thermal burns.

Further, heat is known to add to the problem of venous insufficiency as heat dilates veins and will increase fluid retention in lower extremities and discomfort. In addition, many doctors caution their patients with this condition to avoid any exposure to direct heat for this reason including: heaters, stoves, and even hot showers in the morning. (See Dr. Rivlin, a vascular surgeon known for treating venous insufficiency at <http://www.veincenter.com/chronic.html>). In addition other physicians, have noted that heat, in some cases can be directly attributed to the cause of venous insufficiency, as heat has been noted to damage veins and prevent them from closing properly and allowing fluid to pool in the lower extremities.

A person of ordinary skill in the art would look to avoid heat for the reasons stated above. As a result, the references provided by the Examiner are not properly combinable to result in the invention as claimed.

The combination of Gold’s sock and Sabin et al’s pack would not result in the structure of the claimed invention. There is no teaching of a pad or structure compatible with compression. A structure for producing heat is not equivalent to structure for receiving pressure. In fact, a pack which gives off heat teaches away from a structure which can be compressed. Contrary to the examiner’s statements as shown by the

references from those skilled in the art, a heat pack is not properly combinable with a stocking and a sleeve for treatment of venous insufficiency.

Claim 1

Gold does not disclose a moldable gel pad. The word “gel” is not used in Gold. A heater pack is not a moldable gel pad and it does not appear from Gold that the reference is using the terms heater pack to mean a moldable gel pad. The heater pack of Sabin is also not a moldable gel pad. The heater pack of Sabin gives off heat and is stiff when giving off heat, it is not moldable when in use. The heater pack of Sabin is not a moldable gel. According to Sabin, in col. 5, lines 24-27: “ ... a preformed stiffenable gel is present to affect the rate of reaction. By adjustment of these two rate-controlling features, persons skilled in the art will be able to select and achieve rates of temperature rise and operating temperature in packs according to the present invention.” The pack of Sabin stiffens to allow for an increase in temperature. The gel is used in Sabin to modulate temperature. There is no teaching, suggestion, or motivation in Gold in view of Sabin to arrive at a moldable gel pad structure as claimed.

The use of Gold in view of Sabin would not be practical for two reasons: 1) the heat pack of Sabin gives off heat and would not be able to molded when hot due to its increased stiffness at higher temperatures, and 2) at high temperatures it would not be able to touched safely in order to be molded by hand or placed close to the skin. Claim 1, as amended, is believed to be allowable for the reasons stated above.

Claim 2

_____ Claim 2 of the instant application recites “an opening in said sleeve for accessing, placing and positioning a moldable gel pad within said sleeve”. Gold in view of Sabin lacks this opening structure. Sabin does not have any teaching of an opening in the sleeve. Gold also lacks the claimed sleeve and instead uses a sealed chamber .

Further, Gold explicitly teaches away from the recited structure in Col. 5., lines 20-32. In this passage, Gold teaches stating the need for sealing for two main reasons : 1) the chamber is taught to be closed to prevent heat loss; and 2) sealing the chamber prevents the inadvertent insertion of fingers into the opening which could lead to damage to the device in Gold. These teachings demonstrate that a sealed chamber for holding a heater pack is not equivalent to the claimed elements of a stocking with a sleeve for positioning a moldable gel pad. Further, a person of ordinary skill in the art interested in optimizing heat transfer with a sealed chamber of Gold in combination with the heat pack of Sabin would not result in the structure as claimed.

MPEP section 2143.01 indicates that the prior art must suggest the desirability of the claimed invention. “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. ‘The test for an implicit showing is what the combined teachings, knowledge of

one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.’ Here, it is respectfully suggested that the Examiner is improperly combining the references. There is no basis for combining the references as no teaching, suggestion, or motivation is found in the references to arrive at the instant invention as claimed. As a result, claim 2 is not made obvious by Gold in view of Sabin. As a result, claim 2 is allowable for the reasons stated above as well as for its dependence on claim 1 which is allowable.

Claims 3, 4, and 6

Claim 3 recites a compression stocking and a moldable gel pad. Claims 4 and 6 are dependent on claim 3.

Gold and Gold in view of Sabin both lack a compression stocking. In fact, the words “compress”, “compression”, and “stocking” are not even used in the Gold disclosure. Sabin also lacks any teaching, suggestion, or motivation towards a compression stocking, as this reference also lacks the words “compress”, “compression”, and “stocking”. Sabin discloses a heater pack which gives off heat. **Sabin teaches away from compression as heat is not properly combinable with compression for the treatment of venous insufficiency. As stated above previously, heat is to be avoided and heat with compression could have serious negative consequences on the surface of the skin as well as the treatment of venous insufficiency.**

There is no teaching, suggestion, or motivation in either reference whether used

alone or in combination to arrive at the missing compression stocking structure.

Gold also lacks a moldable gel pad and as discussed above, Sabin also lacks a moldable gel pad. Sabin discloses a heater pack. However, this pack can not be considered as a moldable gel pad, because there is no teaching, suggestion, or motivation contained in the specification to describe molding or shaping it as in the instant invention. Further, the heater pack of Sabin has a set shape with a defined outer boundaries. It is large and it is a teaching of Sabin that this large heater pack can be positioned on the outer circumference of a limb. This is contrary to the moldable gel pad of the instant invention which can be shaped and does not have a large set outer perimeter. There is no teaching, suggestion, or motivation to arrive at the moldable gel pad structure as claimed. Compression stockings are known in the art as set forth in applicant's specification referring to US Patent No. 5,823,195. The sock depicted in Figs. 6 and 7 of Gold is not a compression stocking. As discussed above Sabin also lacks a moldable gel pad. Both Gold and Sabin disclose structure for the release of heat. Heat is not the same as compression. Further, there is no teaching, suggestion, or motivation in Gold in view of Sabin that would allow one of ordinary skill in the art to arrive at the invention as claimed.

As a results claims 3, 4, and 6 are believed to be allowable and are not made obvious by Gold in view of Sabin.

Claim 5

Claim 5 recites a stocking including a folded portion and a stitched portion to form a sleeve. The folded and knit portions bound the sleeve in the instant application. Both Gold and Sabin and Gold in view of Sabin lack a sleeve formed by a folded structure. Claim 5 is believed to be allowable.

Claim 9

Claim 9 recites a device for treating venous insufficiency comprising an understocking having a sleeve and a moldable gel pad within the sleeve. Gold in view of Sabin lacks the claimed elements of an understocking having a sleeve and moldable gel pad within the sleeve. The Gold reference lacks a moldable gel pad and any teaching for using a moldable gel pad to treat venous insufficiency. Sabin also lacks a moldable gel pad. As a result, Gold in view of Sabin lacks any teaching, suggestion, or motivation to arrive at the claimed structure.

Gold further explicitly teaches away from the instant application in suggesting stiffening structure which is much different from the moldable gel pad of the instant invention. (See Col. 8, lines 30-33 and Col. 4 , line 65- Col. 5, line 3). Gold explicitly teaches that the heater pack 34 is activated to produce heat prior to placing the heater pack into the pocket. According, to Sabin in Col. 2, lines 25-41, the activation of the heater pack also stiffens the heater pack. As a result, Gold in view of Sabin would result in the insertion of an activated heater pack which is stiff and which is inserted within a sleeve and not moldable. This teaches away from the structure of the instant invention

which claims a moldable gel within a sleeve.

Further, the instant invention teaches an understocking to be used compatibly with a moldable gel pad within a sleeve for treating venous insufficiency. There is no teaching in either reference for using a moldable gel pad to treat venous insufficiency. Both references teach the use of heat, there is no teaching for the gel pad to be moldable and located within the sleeve of an understocking. In fact, Gold in view of Sabin, teaches away from the instant invention, in that Sabin teaches the use of a heat pack “ around a limb” Col. 17, line 20 or on “ extensive body surfaces such as the back or chest of a human” Col. 17, lines 26-27. Use of the large heater pack structure of Sabin around an entire limb would not enable a moldable gel pad be used to treat venous insufficiency. Further, the heat from the Gold-Sabin combination could not be used for treating venous insufficiency as it would not have the required effect to reduce venous insufficiency.

MPEP section 2143.01 indicates that the prior art must suggest the desirability of the claimed invention. “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. ‘The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.’ Here, it is respectfully

suggested that the Examiner is improperly combining the references. There is no basis for combining the references as no teaching, suggestion, or motivation is found in the references to arrive at the instant invention as claimed. As a result, claim 9 is not made obvious by Gold in view of Sabin and claim 9 is allowable.

Claim 10

Claim 10 is dependent on claim 9 and is allowable at least for the reasons stated above as well as for the additional structure of claim 10. Claim 10 recites a device for treating venous insufficiency comprising an opening for accessing, placing, and positioning a moldable gel pad within the sleeve.

Both Gold and Sabin separately and when taken together teach away from this device. As the heat pack in Sabin is large, it is placed and positioned around the circumference of the wearer's limb (Col. 17, lines 12-24 of Sabin). Further, Gold teaches a nylon strap 40 and a sealed chamber 450. Gold lacks the opening for accessing, placing, and positioning a moldable gel pad within the sleeve. Gold teaches in Col. 7, line 32 that: "there is no apparent opening which might mistakenly receive the wearer's foot when the sock is put on." Gold further explicitly teaches away from the instant application in suggesting stiffening structure that teaches away from the moldable gel pad of the instant invention. (See Col. 8, lines 30-33 and Col. 4 , line 65- Col. 5, line 3). Gold explicitly teaches that the heater pack 34 is activated to produce prior to placing the heater pack into the pocket. According, to Sabin in Col. 2, lines 25-41, the activation of the

heater pack will stiffen the heater pack. As a result, Gold in view of Sabin teaches away from the structure of the instant invention. As a result, claim 10 is believed to be allowable and is not made obvious by Gold in view of Sabin.

Claim 11

Claim 11 is dependent on claim 10 and indirectly dependent on claim 9 and is allowable at least for the reasons that both claims 9 and 10 are allowable. Further, claim 11 recites a compression stocking. This structure is totally missing from either reference as well as Gold in view of Sabin. The structure of a compression stocking is not properly combinable with the structure of Knox in view of Sabin. As discussed above, there is no teaching, suggestion, or motivation in either reference to use compression with the large heat pack of Sabin.

Most importantly, both references have structural elements that are not properly combinable with a compression stocking and teach away from the compression stocking structure to treat venous insufficiency. Firstly, heat is not equivalent to compression. The heater pack structures of Gold and Sabin are not properly combinable to arrive at the claimed compression stocking structure of the instant invention. Combining the heater packs of Gold and Sabin with a compression stocking could result in a severe burn to the skin.

Secondly, both Gold and Sabin teach away from compression. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize

heat transmission. A compression stocking would not be able to maximize the transmission of air as taught in Gold. Secondly, the large heater pack of Sabin which is taught to be applied an entire limb, would not be conducive to the application of pressure to a specific area of the foot, leg, or ankle to reduce venous insufficiency as in the instant invention.

There is no reason a person of ordinary skill in the art would be able to combine the structure of Gold and Sabin to arrive at the structure as claimed. Both Gold and Sabin lack the compression stocking structure recited in claim 11. Further, the heater pack structures of Gold in Sabin are not compatible with a moldable gel pad held in a compression stocking.

As a result, claim 11 is believed to be allowable for the reasons stated above as well as for its dependence on claim 10.

Claim 12

Claim 12 is dependent on claim 9 and is allowable for at least the reasons that claim 9 is allowable. Additionally, claim 12 recites a compression stocking. Claim 12 is allowable for the same reasons stated above that claim 11 which also recites a compression stocking is allowable. Gold and Sabin as well as Gold in view of Sabin simply lack this structure.

As a result, Claim 12 is believed to be allowable.

Claim 13

Claim 13 is dependent on claim 9 and is allowable for at least the reasons stated above.

Claim 13 requires an understocking having folded and stitched portions forming a sleeve. The Gold reference in view of Sabin does not disclose the elements or limitations of claims 13. Sabin entirely lacks an understocking having a sleeve. Further, the Gold reference has a sock with a sealed chamber, but lacks an understocking having a sleeve formed by folded and stitched portions. The words “folded”, “folds”, or “fold” do not appear anywhere in the Gold disclosure. Claim 13 is not made obvious by Gold in view of Sabin and claim 13 is allowable.

Claim 14

Claim 14 is dependent on claim 13 requires an understocking made from the group of materials selected from nylon, polyester, and cotton. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize heat transmission. Gold teaches the use of materials to maximize the transmission of heat. Increased gaps to allow for increased transmission of heat, in Gold would teach away from the structure of an understocking which fits close to the skin. There is no teaching, suggestion, or motivation found in Gold to result in the structure of the claimed invention. Claim 14 is believed to be allowable for at least the reasons claims 9 and 13 are allowable, as well for the reasons stated above.

Claim 15

Claim 15 recites an understocking made from an elastic material. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize heat transmission. This mesh teaches away from the structure of an understocking made from an elastic material as claimed in the instant invention which would close fitting to the skin and reduce passage of air and transmission of heat. Claim 15 is believed to be allowable for at least the reasons claims 9 and 13 are allowable, as well for the reasons stated above.

Claim 16-19

Claims 16 -19 are method claims for reducing venous insufficiency. Claim 16, as amended, includes the step of “positioning a moldable gel pad about said foot, ankle and leg of said patient to apply pressure to reduce venous insufficiency. “Neither, Gold Sabin, nor Gold in view of Sabin include the elements of a moldable gel pad for applying pressure. The heater pack in Gold is located in a sealed chamber 450 and attached to a strap 40 for easier exchange of the heater pack. The seal chamber 450 is located on the top of the foot or the bottom of the sock 400. These locations are different from the claimed invention and these locations would not be able to apply pressure to reduce venous insufficiency or in specific locations about the ankle or leg. There is no teaching in either reference to apply pressure about the ankle or leg to apply pressure to reduce venous insufficiency. Gold in view of Sabin lacks the structure of a moldable gel pad located about the ankle or leg to apply pressure to reduce venous insufficiency.

Most importantly, the elements of Gold and Sabin are not properly combinable to result in a treatment for venous insufficiency. Those skilled in the art teach the avoidance of heat for the treatment of venous insufficiency. There would be no reason for a person of ordinary skill in the art to do something contrary to conventional medical wisdom and which would increase the problem and may cause burns to the surface of the skin.

As stated previously, Gold in view of Sabin lacks a moldable gel pad. Further, there is no teaching found in either Gold or Sabin to use a moldable gel pad to apply pressure to reduce insufficiency. Further, it would not be possible to apply pressure to reduce venous insufficiency with the heater pack of either reference. The heater pack in Gold is only capable of fitting in a set chamber location on the foot and is not located in the position on the leg and ankle necessary to reduce venous insufficiency. Secondly, the heater pack in Sabin is too large to apply pressure to reduce venous insufficiency. As described in the Sabin disclosure, the heater pack is typically fit around an entire limb or over a large surface such as the back. There is no way this large heater pack could be used to apply pressure to reduce the pressure in a small area of the leg or ankle to reduce venous insufficiency. As stated previously, the Gold reference teaches the insertion of an activated heat pack into the chamber, the heater pack of Sabin is stiff when activated, as a result Gold in view of Sabin, would not result in the insertion of moldable gel pack into the understocking. Gold in view of Sabin teaches away from the claimed invention.

Additionally, the heat pack of Sabin is not equivalent to pressure or even properly combinable to arrive at the structure of the claimed invention. The devices of both Sabin and Gold release heat. The release of heat is not equivalent in any way to the application of pressure. The release of heat can not be used to reduce venous insufficiency as in the claimed invention.

MPEP section 2143.01 quoted above indicates that the prior art must suggest the desirability of the claimed invention. Here, it is respectfully suggested that there is no basis for combining Gold and Sabin to result in the structure as claimed. Neither Gold nor Sabin teach any of the process steps recited in claims 16-19. Specifically, Gold and Sabin do not teach positioning a moldable gel pad within a sleeve of an understocking worn by a patient. Nor do the references hint about the stocking being a compression stocking or the overstocking being a compression stocking. Sabin's heat pack which is stiff cannot mold to fit the recesses which are located about an ankle. The moldable gel pad of the claimed invention cannot be replaced by a stiff heat pack. Both references lack structure, teaching, suggestion, and motivation to render the claims obvious. As a result, claims 16-19 are not made obvious by Gold in view of Sabin. Reconsideration of claims 16-19 is requested.

Claim 21

Claim 21 is dependent on claim 1. Claim 1 is allowable for at least the reasons stated above in addition claim 21 recites a material that is soft and pliable. The material of

the heater pack in Gold in view of Sabin is not soft or pliable. The heater pack of Sabin when activated releases heat and stiffens. This heater pack is then not able to be bent and reshaped as expected from a pliable material. Once the material is bent, activation occurs and the heater pack is no longer shapeable because of the resulting stiffness and the higher temperature of the heater pack of Sabin. Further, the heater pack of Sabin has a set perimeter which can not be reshaped easily before or after the exothermic reaction.

Claim 22

Claim 22 is dependent on claim 2 and is allowable for at least the reasons that claim 2 is allowable. Claim 22 has further limitations that are not found in Gold in view of Sabin. Claim 22 recites a stocking which fits over a bodily appendage where the bodily appendage has an exterior surface with surface contours. Claim 22 further recites a moldable gel pad which is small and thin and fits in surface contours of bodily appendage. Gold in view of Sabin lacks any teaching to apply a moldable gel pad in the surface contours of a bodily appendage. Both Sabin and Gold recite a large device which is located on the outer circumference of a limb. Sabin, in particular, describes using the heating device on a large exterior surface of the body such as the back or the chest. (See Sabin, Col. 17, line 25) Further, both Gold and Sabin lack a moldable gel pad as discussed above. Further, both references also lack a moldable gel pad which is small and thin. Based on the reasons stated above as well as its dependence on claim 2, claim 22 is not made obvious by Gold in view of Sabin, and is allowable.

Claim 23

Claim 23 is dependent on claim 3 and is allowable for at least the reasons that claim 3 is allowable. Claim 23 has further limitations that are not found in Knox in view of Sabin. Claim 23 recites a compression stocking which fits over a bodily appendage where the bodily appendage has projections. Claim 23 further recites a moldable gel pad which is held into place in proximity to projections of the bodily appendage and provides a desired distribution of pressure between the compression stocking and the bodily appendage. Gold in view of Sabin lacks any teaching to apply a moldable gel pad in proximity to projections of a bodily appendage. Both Sabin and Gold recite a large device which is located on the outer circumference of a limb. Sabin, in particular, describes using the heating device on a large exterior surface of the body such as the back or the chest. (See Sabin Col. 17, line 25). Gold recites only two fixed locations for inserting the heater pack. Both of these locations are fixed and neither are near projections of the bodily appendage. Further, these devices would not be able to be placed in proximity to projections as taught in the instant application.

Further, both references also lack a compression stocking and any teaching, suggestion, or motivation to provide the claimed desired distribution of pressure between the compression stocking and bodily appendage. The references include heater packs which release heat, they do not provide any teaching with respect to the distribution of pressure. As stated previously, neither reference includes the words “compress” or

“compression” anywhere in their disclosure. Based on the reasons stated above as well as its dependence on claim 3, claim 23 is not made obvious by Gold in view of Sabin, and is allowable.

Claim 24

Claim 24 recites a stocking for use in combination with a bodily appendage where the stocking contains a compartment with a moldable gel pad. The moldable gel pad is placed in proximity to the surface irregularities of the bodily appendage. Gold in view of Sabin does not provide any teaching, suggestion, or motivation to place a moldable gel pad in proximity to surface irregularities of a bodily appendage. Further, Gold does not contain any teaching, suggestion, or motivation to locate the heater packs near any surface irregularities. The heater pack in Gold is only taught to be located on two locations on the foot and nowhere on the ankle or leg near surface irregularities. The heater device in Sabin locates this large device on the outer circumference of a bodily appendage. There is no teaching, suggestion, or motivation found in either reference or in Gold in view of Sabin to arrive at the structure as claimed. Claim 24 is not made obvious by Gold in view of Sabin. As a result, claim 24 is believed to be allowable.

Claims 1-6, 9-19, and 21-24 were rejected under 35 U.S.C. 103 (a) as being unpatentable over Gold (U.S. Patent No. 5, 187,814) further in view of Beisang, III et al (US Patent No. 4, 596,250).

Both references teach the use of a heat pack, however, a pack that supplies heat

has nothing to do with the instant invention. A stiff pack that supplies heat in the reference is structurally different from a gel pad that can be placed safely near the surface of the skin. The invention of the instant application claims a moldable gel pad, both references teach “a pack”, a heat pack is not a moldable gel pad. As a result, the invention of the instant application is not made obvious, by Gold in view of Beisang, and claims 1-6, 8-19, and 21-24 are patentable.

Further, applicant strongly disagrees with the Examiner’s statement on page 5, line 10. The Examiner states that:” The Gold device would be capable of performing the method of treating a patient having venous insufficient [sic] via Gold’s sock using Sabin [sic] et al’s gel pack. “It would not be possible to use Gold’s sock with Beisang et al’s gel pack to treat a patient having venous insufficiency.

Most importantly, the elements of Gold and Beisang et al’s are not properly combinable to result in a treatment for venous insufficiency. Those skilled in the art teach the avoidance of heat for the treatment of venous insufficiency. There would be no reason for a person of ordinary skill in the art to do something contrary to conventional medical wisdom and which would increase the problem of venous insufficiency and may cause burns to the surface of the skin.

Further, the heat of Beisang et al’s heat/cooling pack is not the same as a gel pad. The application of pressure in the instant invention is different from the use of heat in the references. The combination of Gold’s sock and Beisang et al’s gel pack would not result

in the structure of the claimed invention. There is no teaching of a pad or structure compatible with compression. A structure for producing heat is not equivalent to structure for receiving pressure. In fact, a pack which gives off heat teaches away from a structure which can be molded. Contrary to what the Examiner says, a heat pack is not properly used to treat venous insufficiency.

Compression stockings are known in the art as set forth in applicant's specification referring to US Patent No. 5,823,195. The sock depicted in Figs. 6 and 7 of Gold is not a compression stocking. As discussed above Beisang also lacks a moldable gel pad. Both Gold and Beisang disclose structure for the release of heat. Heat is not the same as a moldable gel pack. Further, there is no teaching, suggestion, or motivation in Gold in view of Beisang that would allow one of ordinary skill in the art to arrive at the invention as claimed.

Claims 1 and 2

Gold has been studied. Gold does not disclose a moldable gel pad. The word "gel" is not used in Gold. A heater pack is not a moldable gel pad and it does not appear from Gold that the reference is using the terms heater pack to mean a moldable gel pad. The heater pack of Beisang is also not a moldable gel pad. Beisang discloses a moldable cooling/heating device used for cooling/heating body organs or parts.

There is no teaching, suggestion, or motivation to combine Gold with Beisang to result in the structure as claimed. Beisang provides a resting surface for an organ. Beisang

teaches maximizing the cooling surface area in contact with the organ by wrapping-around the organ. Beisang also teaches that body tissue can be damaged from too hot or too cold a temperature, Col. 3, lines 40-42. The storage medium changes from semi-solid to liquid form. Claims 1 and 2 are believed to be allowable for the reasons stated above.

Claims 3, 4, and 6

Claim 3 recites a compression stocking and a moldable gel pad. Claims 4 and 6 are dependent on claim 3.

Gold in view of Beisang lacks a compression stocking. In fact, the words “compress”, “compression”, and “stocking” are not even used in the Gold disclosure. Beisang also lacks any teaching, suggestion, or motivation towards a compression stocking, as this reference also lacks the words “compress”, “compression”, and “stocking”. Beisang discloses a heater pack which gives off heat. There is no teaching, suggestion, or motivation in either reference whether used alone or in combination to arrive at the missing compression stocking structure.

Gold also lacks a moldable gel pad and as discussed above Beisang also lacks a moldable gel pad. Beisang discloses a heater pack. However, this pack cannot be considered as a moldable gel pad, because there is no teaching, suggestion, or motivation in the specification to describe molding or shaping it as in the instant invention. Further, the heater pack of Beisang has a set shape with defined outer boundaries. It is large and it is a teaching of Beisang that this large heater pack can be positioned on the outer

circumference of a limb. This is contrary to the moldable gel pad of the instant invention which can be shaped and does not have a large shape with a well-defined perimeter. There is no teaching, suggestion, or motivation to arrive at the moldable gel pad structure as claimed.

As a results claims 3, 4, and 6 are believed to be allowable and are not made obvious by Gold in view of Beisang.

Claim 5

Claim 5 recites a stocking including a folded portion and a stitched portion to form a sleeve. The folded and knit portions bound the sleeve in the instant application. Gold in view of Beisang lacks a sleeve formed by a folded structure. Claim 5 is believed to be allowable.

Claim 9

Claim 9 recites a device for treating venous insufficiency comprising an understocking having a sleeve and a moldable gel pad within the sleeve. Gold in view of Beisang lacks the understocking having a sleeve and moldable gel pad within the sleeve. The Gold reference lacks a moldable gel pad and any teaching for using a moldable gel pad to treat venous insufficiency. Beisang also lacks a moldable gel pad. As a result, Gold in view of Beisang lacks the necessary teaching, suggestion, or motivation to arrive at the claimed structure.

Gold further explicitly teaches away from the instant application in suggesting an

activated heater pack which results in a stiffening structure (See Gold Col. 8, lines 30-33 and Col. 4 , line 65- Col. 5, line 3). Gold explicitly teaches that the heater pack 34 is activated prior to placing the heater pack into the pocket. According, to Beisang in Col. 2, lines 25-41, the activation of the heater pack also stiffens the heater pack. As a result, Gold in view of Beisang would result in the insertion of activated heater pack which is stiff and not moldable. This teaches away from the structure of the instant invention which claims a moldable gel within a sleeve.

Further, the instant invention teaches an understocking to be used compatibly with a moldable gel pad within a sleeve for treating venous insufficiency. There is no teaching in either reference for using a moldable gel pad to treat venous insufficiency. Both references teach the use of heat, there is no teaching for the gel pad to be moldable and be located within the sleeve of an understocking. In fact, Gold in view of Beisang, teaches away from the instant invention, in that Beisang teaches the use of a heat pack “around a limb” Col. 17, line 20 or on “extensive body surfaces such as the back or chest of a human” Col. 17, lines 26-27. Use of the large heater pack structure of Beisang around an entire limb would not result in the claimed element of a gel pad in a sleeve. Further, it would not enable a moldable gel pad be used to treat venous insufficiency. Most importantly, the heated structure of Gold in view of Beisang could not be used for treating venous insufficiency as it would not have the required effect to reduce venous insufficiency.

MPEP section 2143.01 indicates that the prior art must suggest the desirability of the claimed invention. “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. ‘The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.’ Here, it is respectfully suggested that the Examiner is improperly combining the references. There is no basis for combining the references as no teaching, suggestion, or motivation is found in the references to arrive at the instant invention as claimed. As a result, claim 9 is not made obvious by Gold in view of Beisang and claim 9 is allowable.

Claim 10

Claim 10 is dependent on claim 9 and is allowable at least for the reasons stated above as well as for the additional structure of claim 10. Claim 10 recites a device for treating venous insufficiency comprising an opening for accessing, placing, and positioning a moldable gel pad within the sleeve.

Both Gold and Beisang separately and when taken together teach away from this structure. As the heat pack in Beisang is large, it is placed and positioned around the circumference of the wearer’s limb (Col. 17, lines 12-24 of Beisang). Further, Gold

teaches a nylon strap 40 and a sealed chamber 450. Gold lacks the opening for accessing, placing, and positioning a moldable gel pad within the sleeve. Gold teaches in Col. 7, line 32 that: “ there is no apparent opening which might mistakenly receive the wearer’s foot when the sock is put on.” Gold further explicitly teaches away from the instant application in suggesting stiffening structure that teaches away from the moldable gel pad of the instant invention. (See Gold, Col. 8, lines 30-33 and Col. 4 , line 65- Col. 5, line 3). As a result, claim 10 is believed to be allowable and is not made obvious by Gold in view of Beisang.

Claim 11

Claim 11 is dependent on claim 10 and indirectly dependent on claim 9 and is allowable at least for the reasons that both claims 9 and 10 are allowable. Further, claim 11 recites a compression stocking. This structure is totally missing from either reference as well as Gold in view of Beisang. The structure of a compression stocking is not properly combinable with the structure of Knox in view of Beisang. As discussed above, there is no teaching, suggestion, or motivation in either reference to use compression with the large heat pack of Beisang.

Most importantly, both references have structural elements that are not properly combinable with a compression stocking and teach away from the compression stocking structure to treat a venous insufficiency. Firstly, heat is not equivalent to compression. Combining the heater packs of Gold and Beisang with a compression stocking could

result in a severe burn to the skin.

Secondly, both Gold and Beisang teach away from compression. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize heat transmission. A compression stocking would not be able to maximize the transmission of as taught in Gold. The large heater pack of Beisang which is taught to be applied an entire limb, would not be conducive to the application of pressure to a specific area of the foot, leg, or ankle to reduce venous insufficiency as in the instant invention.

There is no reason a person of ordinary skill in the art would be able to combine the structure of Gold and Beisang to arrive at the structure as claimed. Both Gold and Beisang lack the compression stocking structure of the instant invention. Further, the heater pack structures of Gold in Beisang are not compatible with a moldable gel pad held in a compression stocking. As a result, claim 11 is believed to be allowable for the reasons stated above as well as for its dependence on claim 10.

Claim 12

Claim 12 is dependent on claim 9 and is allowable for at least the reasons that claim 9 is allowable. Additionally, claim 12 recites a compression stocking. Claim 12 is allowable for the same reasons stated above that claim 11 which also recites a compression stocking is allowable. Gold in view of Beisang simply lacks this structure.

As a result, Claim 12 is believed to be allowable.

Claim 13

Claim 13 is dependent on claim 9 and is allowable for at least the reasons stated above.

Claim 13 requires an understocking having folded and stitched portions forming a sleeve. The Gold reference in view of Beisang does not disclose the elements or limitations of claims 13. Beisang entirely lacks an understocking having a sleeve. Further, the Gold reference has a sock with a sealed chamber, but lacks an understocking having a sleeve formed by folded and stitched portions. The words “folded”, “folds”, or “fold” do not appear anywhere in the Gold disclosure. Claim 13 is not made obvious by Gold in view of Beisang and claim 13 is allowable.

Claim 14

Claim 14 is dependent on claim 13 and requires an understocking made from the group of materials selected from nylon, polyester, and cotton. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize heat transmission. Gold teaches the use of materials to maximize the transmission of heat. Increased gaps allow increased transmission of heat. Gold teaches away from the structure of an understocking which fits close to the skin. There is no teaching, suggestion, or motivation found in Gold to result in the structure of the claimed invention. Claim 14 is believed to be allowable for at least the reasons claims 9 and 13 are allowable, as well for the reasons stated above.

Claim 15

Claim 15 recites an understocking made from an elastic material. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize heat transmission. This mesh teaches away from the structure of an understocking made from an elastic material as claimed in the instant invention which would close fitting to the skin and reduce passage of air and transmission of heat. Claim 15 is believed to be allowable for at least the reasons claims 9 and 13 are allowable, as well for the reasons stated above.

Claim 16-19

Claims 16 -19 are method claims for reducing venous insufficiency. Claim 16, as amended, includes the step of “positioning a moldable gel pad about said foot, ankle and leg of said patient to apply pressure to reduce venous insufficiency. “ Neither, Gold Beisang, nor Gold in view of Beisang include the elements of a moldable gel pad for applying pressure. The heater pack in Gold is located in a sealed chamber 450 and attached to a strap 40 for easier exchange of the heater pack. The seal chamber 450 is located on the top of the foot or the bottom of the sock 400. These locations are different from the claimed invention and these locations would not be able to apply pressure to reduce venous insufficiency or in specific locations about the ankle or leg. There is no teaching in either reference to apply pressure about the ankle or leg to apply pressure to reduce venous insufficiency. Gold in view of Beisang lacks the structure of a moldable gel pad located about the ankle or leg to apply pressure to reduce venous insufficiency.

As stated previously, Gold in view of Beisang lacks a moldable gel pad. Further, there is no teaching found in either Gold or Beisang to use a moldable gel pad to apply pressure to reduce insufficiency.

Further, it would not be possible to apply pressure to reduce venous insufficiency with the heater pack of either reference. The heater pack in Gold is only capable of fitting in a set chamber location on the foot and is not located in the position on the leg and ankle necessary to reduce venous insufficiency. Secondly, the heater pack in Beisang is too large to apply pressure to reduce venous insufficiency. As described in the Beisang disclosure, the heater pack is typically fit around an entire limb or over a large surface such as the back. There is no way this large heater pack could be used to apply pressure to reduce the pressure in a small area of the leg or ankle to reduce venous insufficiency. As stated previously, the Gold reference teaches the insertion of an activated heat pack into the chamber, the heater pack of Beisang is stiff when activated, as a result Gold in view of Beisang, would not result in the insertion of moldable gel pack into the understocking. Gold in view of Beisang teaches away from the claimed invention.

Further, the heat pack of Beisang is not equivalent to pressure or even properly combinable to arrive at the structure of the claimed invention. The devices of both Beisang and Gold release heat. The release of heat is not equivalent in any way to the application of pressure. The release of heat can not be used to reduce venous insufficiency as in the claimed invention.

Most importantly, the elements of Gold and Beisang et al's are not properly combinable to result in a treatment for venous insufficiency. Those skilled in the art teach the avoidance of heat for the treatment of venous insufficiency. There would be no reason for a person of ordinary skill in the art to do something contrary to conventional medical wisdom and which would increase the problem of venous insufficiency and may cause burns to the surface of the skin.

MPEP section 2143.01 indicates that the prior art must suggest the desirability of the claimed invention. Here, it is respectfully suggested that there is no basis for combining Gold and Beisang to result in the structure as claimed. Neither Gold nor Beisang teach any of the process steps recited in claims 16-19. Specifically, Gold and Beisang do not teach positioning a moldable gel pad within a sleeve of an understocking worn by a patient. Nor do the references hint about the stocking being a compression stocking or the overstocking being a compression stocking. Beisang's heat pack which is stiff cannot mold to fit the recesses which are located about an ankle. The moldable gel pad of the claimed invention cannot be replaced by a stiff heat pack. Both references lack structure, teaching, suggestion, and motivation to render the claims obvious. As a result, claims 16-19 are not made obvious by Gold in view of Beisang. Reconsideration of claims 16-19 is requested.

Claim 21

Claim 21 is dependent on claim 1. Claim 1 is allowable for at least the reasons

stated above. In addition, claim 21 recites a material that is soft and pliable. The material of the heater pack in Gold in view of Beisang is not soft or pliable. The heater pack of Beisang when activated releases heat and stiffens. This heater pack is then not bendable and shapeable as expected from a pliable material. Once the material is bent, activation occurs and the heater pack is no longer able to shaped because of the resulting stiffness and the higher temperature of the heater pack of Beisang. Further, the heater pack of Beisang has a set perimeter which can not be reshaped easily before or after the exothermic reaction.

Claim 22

Claim 22 is dependent on claim 2 and is allowable for at least the reasons that claim 2 is allowable. Claim 22 has further limitations that are not found in Gold in view of Beisang. Claim 22 recites a stocking which fits over a bodily appendage where the bodily appendage has an exterior surface with surface contours. Claim 22 further recites a moldable gel pad which is small and thin and fits in surface contours of the bodily appendage. Gold in view of Beisang lacks any teaching to apply a moldable gel pad in the surface contours of a bodily appendage. Both Beisang and Gold recite a large device which is located on the outer circumference of a limb. Beisang, in particular, describes using the heating or cooling device on as large surface area of an organ as possible (See Beisang Col. 1, lines 28-32 and Beisang Col. 3, line 29-32). **Gold in view of Beisang teaches away from the instant invention in that they both lack structure to be placed**

in surface contours of a bodily appendage. Gold in view of Beisang discloses structure to effect a change in temperature, both references lack teaching to adjust to and fit in the surface of an appendage. Gold's device has a fixed chamber assembly and Beisang teaches a wrap around structure around the entire organ to optimize heat transfer by increasing surface area of contact between the device and the organ. Whether taken alone or in combination, there is no teaching that would allow one of ordinary skill in the art to arrive at the structure as claimed.

Further, both Gold and Beisang lack a moldable gel pad as discussed above. Further, both references also lack a small and thin moldable gel pad. Based on the reasons stated above as well as its dependence on claim 2, claim 22 is not made obvious by Gold in view of Beisang, and is allowable.

Claim 23

Claim 23 is dependent on claim 3 and is allowable for at least the reasons that claim 3 is allowable. Claim 23 has further limitations that are not found in Gold in view of Beisang. Claim 23 recites a compression stocking which fits over a bodily appendage where the bodily appendage has projections. Claim 23 further recites a moldable gel pad which is held into place in proximity to projections of the bodily appendage and provides a desired distribution of pressure between the compression stocking and the bodily appendage. Gold in view of Beisang lacks any teaching to apply a moldable gel pad in proximity to projections of a bodily appendage. Both Beisang and Gold recite a large

device which is located on the outer circumference of a limb. Beisang, in particular, describes using the heating or cooling device to increase surface area in contact between the organ and the device. (See Beisang Col. 1, lines 28-32 and Beisang Col. 3, line 29-32). Gold recites only two fixed locations for inserting the heater pack. Both of these locations are fixed and neither are near projections of the bodily appendage. Further, these devices would not be able to be placed in proximity to projections as taught in the instant application.

Further, both references also lack a compression stocking and any teaching, suggestion, or motivation to provide the claimed desired distribution of pressure between the compression stocking and bodily appendage. The references include heater packs which release heat, they do not provide any teaching with respect to the distribution of pressure. As stated previously, neither reference includes the words “compress” or “compression” anywhere in their disclosure. Based on the reasons stated above as well as its dependence on claim 3, claim 23 is not made obvious by Gold in view of Beisang, and is allowable.

Claim 24

Claim 24 recites a stocking for use in combination with a bodily appendage where the stocking contains a compartment with a moldable gel pad. The moldable gel pad is placed in proximity to the surface irregularities of the bodily appendage. Gold in view of Beisang does not provide any teaching, suggestion, or motivation to place a moldable gel

pad in proximity to surface irregularities of a bodily appendage. Further, Gold does not contain any teaching, suggestion, or motivation to locate the heater packs near any surface irregularities. The heater pack in Gold is only taught to be located on two locations on the foot and nowhere on the ankle or leg near surface irregularities. The heater device in Beisang locates this large device on the outer circumference of a bodily appendage. There is no teaching, suggestion, or motivation found in either reference or in Gold in view of Beisang to arrive at the structure as claimed. Claim 24 is not made obvious by Gold in view of Beisang. As a result, claim 24 is believed to be allowable.

Claims 7 and 8 are rejected under 35 USC 103 (a) as being unpatentable over Gold (U.S. Patent No. 5,187,814), modified by Sabin, et al (U.S. Patent No. 5,984,953) and further in view of Knox (U.S. Patent No. 5,814,003).

Claim 7

Claim 7 is dependent on claims 2 and 5 and is allowable for at least the reasons claims 2 and 5 are allowable. Namely, claim 2 recites a moldable gel pad and claim 5 recites a folded portion to form a sleeve. Gold modified by Sabin and in further view of Knox lacks these claimed elements.

Gold is not properly combinable with Sabin in view of Knox to arrive at the invention recited in claim 7. Knox appears to be a device with an inner sleeve 12 and an outer sleeve for holding a pulsatile bladder without pressing the pulsatile bladder uncomfortably against the limb (See Knox Col. 4, lines 40-61.) This structure has a loose

fit about a limb which enables the pulsatile bladder to move. This structure lacks the folded portion of the structure of the claimed device.

Further, Gold teaches securing heating packs in position to optimize heat transfer to coldest parts of hand without restricting movement. (See Gold Col. 2, lines 1-6 and Gold Col. 6, lines 19-22). Further, as stated previously Sabin lacks a moldable gel pad and teaches the placement of a heat onto a limb or a large bodily surface. Due to the size and stiffness of the heat pack in Sabin and the need to transfer heat over large surface areas there would be no reason to include a heat pack in the sleeve of a stocking. The purpose of Sabin to transfer heat would be more readily achieved by wrapping around the circumference of the limb. Gold, Knox, and Sabin whether used alone or in combination lack certain key structural elements including a folded portion of the sleeve and a moldable gel pad. Further, Gold, Knox, and Sabin whether used alone or in combination teach away from each other. Gold teaches the use of heater packs in a walled chambers in a fixed position, Knox teaches the use of a loose fitting outer sleeve to hold a pulsatile bladder, and Sabin teaches a heat pack which can be placed around a limb. There is no teaching, suggestion, or motivation of the references to combine the references.

Most importantly, the elements of Gold, Sabin, and Knox are not properly combinable to result in a treatment for venous insufficiency. Those skilled in the art teach the avoidance of heat for the treatment of venous insufficiency. In the field of medicine, heat is known to dilate blood vessels which would exacerbate the venous

insufficiency condition. Further, it is commonly known in the field of medicine that the combination of heat packs with compression stockings can result in severe third degree burns. There would be no reason for a person of ordinary skill in the art to do something contrary to conventional medical wisdom and which would increase the problem of venous insufficiency and may cause burns to the surface of the skin.

Claim 7 is not made obvious by Gold , modified by Sabin, and further in view of Knox and as a result claim 7 is believed to be allowable.

Claim 8

As demonstrated above, Gold and Sabin do not render claims 3, 4, and 6 unpatentable from which claim 8 indirectly depends. The inclusion of Knox does not add any of the missing elements. As a result, claim 8 is believed to be allowable for its dependence on claims 3, 4, and 6 which are allowable.

The structure of Knox has a loose fitting sleeve about a limb which enables the pulsatile bladder to move. This structure lacks the compression stocking of the claimed invention. The loose fitting outer sleeve of Knox teaches away from the compression stocking of the instant invention.

Further, Gold teaches securing heating packs in position to optimize heat transfer to the coldest parts of hand without restricting movement. (See Gold Col. 2, lines 1-6 and Gold Col. 6, lines 19-22). Further, as stated previously Sabin lacks a moldable gel pad and teaches the placement of a heat pack onto a limb or a large bodily surface. Due to the

size and stiffness of the heat pack in Sabin and the need to transfer heat over large surface areas there would be no reason to include a heat pack in the sleeve of a stocking. The purpose of Sabin to transfer heat would be more readily achieved by wrapping around the circumference of the limb. The heating elements of both Gold and Sabin teach opposite of the compression structure of claim 8 of the instant invention.

Gold, Knox, and Sabin whether used alone or in combination lack certain key structural elements including a folded portion of the sleeve, a moldable gel pad, and the compression stocking. Further, Gold, Knox, and Sabin whether used alone or in combination teach away from each other. Gold teaches the use of heater packs in a walled chambers in a fixed position, Knox teaches the use of a loose fitting outer sleeve to hold a pulsatile bladder, and Sabin teaches a heat pack which can be placed around a limb. These structures can not be combined to result in a compression stocking.

Most importantly, the elements of Gold, Sabin, and Knox are not properly combinable to result in a treatment for venous insufficiency. Those skilled in the art teach the avoidance of heat for the treatment of venous insufficiency. In particular, heat packs and a compression stocking are not compatible. There would be no reason for a person of ordinary skill in the art to do something contrary to conventional medical wisdom and which would increase the problem of venous insufficiency and may cause burns to the surface of the skin.

As a result, a proper case of prima facie obviousness has not been made Gold in

view of Sabin does not render the instant application obvious and claim 8 is patentable

Claims 7 & 8 were rejected under 35 U.S.C. 103 (a) as being unpatentable over Gold (U.S. Patent No. 5,187,814), modified by Beisang, III et al (U.S. Patent No. 4, 596,250) and further in view of Knox (U.S. Patent No. 5,814,003).

Claim 7

Claim 7 is dependent on claims 2 and 5 and is allowable for at least the reasons claims 2 and 5 are allowable. Namely, claim 2 recites a moldable gel pad and claim 5 recites a folded portion to form a sleeve. Gold modified by Beisang and in further view of Knox lacks these structures.

Gold is not properly combinable with Beisang in view of Knox to arrive at the invention recited in claim 7. Knox appears to be a device with an inner sleeve 12 and an outer sleeve for holding a pulsatile bladder without pressing the pulsatile bladder uncomfortably against the limb (See Knox Col. 4, lines 40-61.) This structure has a loose fit about a limb which enables the pulsatile bladder to move. This structure lacks the folded portion of the structure of the claimed device.

Further, Gold teaches securing heating packs in position to optimize heat transfer to coldest parts of hand without restricting movement. (See Gold Col. 2, lines 1-6 and Gold Col. 6, lines 19-22). As stated previously, Beisang lacks a moldable gel pad and teaches the placement of an organ onto this pack for heating or cooling. In order to optimize heat transfer, a person of ordinary skill in the art would look to increase the

surface area of heat pack in contact with the skin. Due to the size and stiffness of the heat pack in Beisang and the need to transfer heat over large surface areas there would be no reason to include a heat pack in the sleeve of a stocking. The moldable gel pad of the instant application works by a completely different principle where the gel pad may be molded to decrease the surface area of the skin in contact with the gel pad to equalize pressures between surfaces for the treatment of venous insufficiency. There is no teaching, suggestion, or motivation to include the cold/heat pack device of Beisang in the sleeve of a stocking (See Beisang Col. 1, lines 28-32 and Beisang Col. 3, line 29-32). The purpose of Beisang to transfer heat would be more readily achieved by wrapping around the circumference of the limb.

Gold, Knox, and Beisang whether used alone or in combination lack certain key structural elements including a folded portion of the sleeve and a moldable gel pad. Further, Gold, Knox, and Beisang whether used alone or in combination teach away from each other. Gold teaches the use of heater packs in a walled chambers in a fixed position, Knox teaches the use of a loose fitting outer sleeve to hold a pulsatile bladder, and Beisang teaches a heat pack which can be placed around a limb. There is no teaching, suggestion, or motivation of the references to combine the references.

Most importantly, the elements of Gold, Beisang, and Knox are not properly combinable to treat venous insufficiency. Those skilled in the art teach the avoidance of heat for the treatment of venous insufficiency. There would be no reason for a

person of ordinary skill in the art to do something contrary to conventional medical wisdom and which would increase the problem of venous insufficiency and may cause burns to the surface of the skin.

Claim 7 is not made obvious by Gold, modified by Sabin, and further in view of Knox and as a result claim 7 is believed to be allowable.

Claim 8

As demonstrated above, Gold and Beisang do not render claims 3, 4, and 6 unpatentable from which claim 8 indirectly depends. The inclusion of Knox does not add any of the missing elements. As a result, claim 8 is believed to be allowable for its dependence on claims 3, 4, and 6 which are allowable.

The structure of Knox has a loose fitting sleeve about a limb which enables the pulsatile bladder to move. This structure lacks the compression stocking of the claimed invention. The loose fitting outer sleeve of Knox teaches away from the compression stocking of the instant invention.

Further, Gold teaches securing heating packs in position to optimize heat transfer to the coldest parts of hand without restricting movement. (See Gold Col. 2, lines 1-6 and Gold Col. 6, lines 19-22). Further, as stated previously Beisang lacks a moldable gel pad and teaches the placement of a heat onto a limb or a large bodily surface. Due to the size and stiffness of the heat pack in Beisang and the need to transfer heat over large surface areas there would be no reason to include a heat pack in the sleeve of a stocking. The

purpose of Beisang to transfer heat would be more readily achieved by wrapping around the circumference of the limb. The heating elements of both Gold and Beisang teach opposite of the compression structure of claim 8 of the instant invention.

Gold, Knox, and Beisang whether used alone or in combination lack certain key structural elements including a folded portion of the sleeve, a moldable gel pad, and the compression stocking. Further, Gold, Knox, and Beisang teach away from each other. Gold teaches the use of heater packs in a walled chambers in a fixed position, Knox teaches the use of a loose fitting outer sleeve to hold a pulsatile bladder, and Beisang teaches a cooling/heating pack which is contact with an organ in as large as surface area as possible to optimize heat transfer. In fact, Gold in view of Beisang, teaches away from the instant invention, in that Beisang teaches the use of a heat pack to wrap-around more of the organ or body part and provide cooling to a larger surface area.” Col 3, lines 31-32 of Beisang. These structures can not be combined to result in the compression stocking of the claimed invention.

Most importantly, the elements of Gold, Knox, and Beisang are not properly combinable to treat venous insufficiency. Those skilled in the art teach the avoidance of heat in treating venous insufficiency. In particular, heat packs and a compression stocking are not compatible. There would be no reason for a person of ordinary skill in the art to do something contrary to conventional medical wisdom and which would increase the problem of venous insufficiency and may cause burns to the

surface of the skin.

MPEP section 2143.01 indicates that the prior art must suggest the desirability of the claimed invention. “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. ‘The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.’ Here, it is respectfully suggested that the Examiner is improperly combining the references. There is no basis for combining the references as no teaching, suggestion, or motivation is found in the references to arrive at the instant invention as claimed. As a result, claim 8 is not made obvious by Gold modified by Beisang and in further view of Knox and claim 8 is allowable.

_____Further, it would not be possible to apply pressure to reduce venous insufficiency with the heater pack of either reference. The heater pack in Gold is only capable of fitting in a set chamber location on the foot and is not located in the position on the leg and ankle necessary to reduce venous insufficiency. Secondly, the heater pack in Beisang is too large to apply pressure to reduce venous insufficiency. As described in the Beisang disclosure, the heater pack is typically fit around an entire limb or over a large surface.

There is no way this large heater pack could be used to apply pressure to reduce the pressure in a small area of the leg or ankle to reduce venous insufficiency. As stated previously, the Gold reference teaches the insertion of an activated heat pack into the chamber, the heater pack of Beisang is stiff when activated, as a result Gold in view of Beisang, would not result in the insertion of moldable gel pack into the understocking. Gold in view of Beisang teaches away from the claimed invention.

Further, the heat pack of Beisang is not equivalent to pressure or even properly combinable to arrive at the structure of the claimed invention. The devices of both Beisang and Gold release heat. The release of heat is not equivalent in any way to the application of pressure. The release of heat can not be used to reduce venous insufficiency as in the claimed invention.

MPEP section 2143.01 quoted above indicates that the prior art must suggest the desirability of the claimed invention. Here, it is respectfully suggested that there is no basis for combining Gold and Beisang to result in the structure as claimed. Neither Gold nor Beisang teach any of the process steps recited in claims 16-19. Specifically, Gold and Beisang do not teach positioning a moldable gel pad within a sleeve of an understocking worn by a patient. Nor do the references hint about the stocking being a compression stocking or the overstocking being a compression stocking. Beisang's heat pack which is stiff cannot mold to fit the recesses which are located about an ankle. The moldable gel pad of the claimed invention cannot be replaced by a stiff heat pack. Both references lack

structure, teaching, suggestion, and motivation to render the claims obvious. As a result, claims 16-19 are not made obvious by Gold in view of Beisang. Reconsideration of claims 16-19 is requested.

Summary

Applicant claims structure that is different and not made obvious by references cited by the Examiner. Claims 1-19 and 21-24 are allowable. Reconsideration of claims 1-19 and 21-24 is requested.

The undersigned invites a call from the Examiner to expedite the processing and allowance of this patent application.

Respectfully submitted,

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Successful methods of treating leg ulcers

Match ALL

The tried and true, plus the novel and new

Tania J. Phillips, MD

**VOL 105 / NO 5 / MAY 1, 1999 /
POSTGRADUATE MEDICINE**

CME learning objectives

- To review the most common causes of leg ulcer
- To recognize underlying factors that influence choice of therapy
- To become familiar with new therapeutic options

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This page is best viewed with a browser that supports tables

Preview: Some therapies for chronic leg ulcers, such as surgical debridement and split-thickness skin grafting, have been used for many years and still have a role in management. However, several new methods are also available. Among these are multilayer compression-bandage systems, topical recombinant human platelet-derived growth factor, and human skin equivalent for use in grafting, all of which aid in healing and wound closure. In this article, Dr Phillips discusses the role of established as well as novel therapies for chronic ulcer and summarizes other issues in the current standard of care.

As the US population ages, primary care physicians are likely to see increasing numbers of patients with leg ulcers. An estimated 2 million workdays are lost each year in the United States because of this condition, and the medical costs of treating these nonhealing wounds can be enormous.

Leg ulcers can be caused by many factors (table 1 (1)), but most are due to venous disease, arterial insufficiency, or neuropathy, alone or in combination. Diabetes is an especially important underlying condition. Of all lower-extremity amputations performed annually in the United

States (usually because of skin ulcers), 45% to 70% are in patients with diabetes (2). More than 80% of diabetic patients with foot ulcers have neuropathy, and early detection of the condition, and of angiopathy, is essential in preventing and possibly reversing the accelerated development of complications in these patients (2).

Table 1. Causes of leg ulcers

Vascular

Arterial

- Atherosclerosis
- Arteriovenous malformation
- Embolism composed of cholesterol
- Thromboangiitis obliterans

Vasculitic

- Small vessel
 - Atrophie blanche
 - Behçet's syndrome
 - Hypersensitivity vasculitis
 - Lupus erythematosus
 - Rheumatoid arthritis
 - Scleroderma
 - Sjögren's syndrome
- Medium and large vessel
 - Nodular vasculitis
 - Polyarteritis nodosa
 - Wegener's granulomatosis

Lymphatic (lymphedema)

Venous

Neuropathic

- Diabetes
- Syringomyelia
- Tabes dorsalis

Hematologic

- Dysproteinemia
 - Cold agglutinin syndrome
 - Cryoglobulinemia
 - Macroglobulinemia
- Red blood cell disorders
 - Hereditary spherocytosis
 - Polycythemia vera
 - Sickle cell anemia
 - Thalassemia
- White blood cell disorders (leukemia)

Traumatic

- Burns
- Cold injury
- Factitial means
- Pressure injury
- Radiation burn

Neoplastic

- Epithelioma
 - Basal cell carcinoma
 - Squamous cell carcinoma
- Lymphoma
 - Cutaneous T cell
 - Lymphoproliferative
- Metastatic tumors
- Sarcoma (eg, Kaposi's)

Metabolic

Diabetes
Gaucher's disease
Gout
Prolidase deficiency

Infective and infestive Bacterial

Ecthyma, ecthyma gangrenosum
Furuncle
Gram-negative, mycobacterial,
spirochetal infection
Septic emboli
Fungal
Deep fungal infections
Trichophytic granuloma
Insect bites
Protozoal (leishmania)

Miscellaneous

Panniculitis
Necrobiosis lipoidica
Pancreatic fat necrosis
Weber-Christian disease
Necrobiosis lipoidica diabetorum
Pyoderma gangrenosum
Sarcoidosis

Adapted, with permission, from Phillips and Dover (1).

History taking and physical examination

The cause of a leg ulcer should be ascertained before a management plan is implemented. Thorough history taking and physical examination (table 2: not shown) are valuable in determining the cause. Clinical findings in the three most common types of leg ulcers--venous, arterial, and neuropathic--are compared in table 3 (not shown) and described in the following text.

Venous ulcers

Patients with venous ulcers may complain of limb aching and swelling that are worse at the end of the day and relieved by elevation of the limb. Patients may describe a history of previous deep-vein thrombosis, trauma or surgery to the legs, or multiple pregnancies.

Typically, venous ulcers are located between the malleolus and the lower calf, are shallow, and have irregular margins (figure 1: not shown). They can vary from small to nearly encircling the leg. Lower-limb edema is often present, and eczematous changes may be seen. Other associated findings on physical examination include varicosities, dark yellow or red-brown pigmentation, and purpura, signs that result from extravasation of red cells into the skin.

Another common finding is lipodermatosclerosis, which is a chronic, fibrosing, inflammatory process of the dermis and subcutaneous tissue that develops from venous insufficiency. In long-term disease, the entire lower leg is involved and becomes sclerotic and indurated. Chronic lymphedema from recurrent episodes as well as cellulitis and

fibrosis of the ankle joint may eventually occur.

Arterial ulcers

Arterial leg ulcers tend to be painful, especially after exertion or when the leg is elevated. Patients may have a history of smoking, diabetes, or intermittent claudication, which is characterized by pain in the calves or buttocks on exertion and is relieved by rest. With more severe arterial disease, patients may even have pain at rest.

Arterial ulcers tend to occur over bony prominences, at distal sites (eg, the toes), and in areas that are prone to trauma. These ulcers are usually well demarcated and have a "punched out" appearance, and their base is often dry and necrotic. Associated findings in an ischemic limb include shiny, atrophic skin with hair loss and cool extremities.

Neuropathic ulcers

Neuropathic ulcers are seen most often in diabetic patients and result from repeated trauma to insensitive tissues. Symptoms include pain, paresthesia, or anesthesia. These ulcers tend to be located over sites of pressure (eg, metatarsal heads, heels, toes) and typically have a thick surrounding callus (figure 2: not shown). Neuropathic ulcers are often very deep.

Laboratory evaluation

Initial testing should consist of a complete blood cell count (to rule out hematologic disorders) and assessment of fasting blood glucose level and erythrocyte sedimentation rate (which if very high may indicate an underlying connective tissue disorder, vasculitis, or osteomyelitis). In elderly patients, nutritional status can be assessed by checking serum albumin and transferrin levels.

More extensive laboratory evaluation includes rapid plasma reagin assessment and testing for antinuclear and anticardiolipin antibodies, lupus anticoagulant, rheumatoid factor, antithrombin III, proteins C and S, cryoglobulins, cryofibrinogens, activated protein C resistance and factor 5 Leiden, and hepatitis A and C antibodies. If a connective tissue disease or hypercoagulable state is suspected, hepatitis B surface antigen should be sought.

Curettage or biopsy of the ulcer for bacterial culturing and sensitivity testing may be done to establish a baseline finding. If ulcers do not improve after 3 to 4 months of treatment, follow-up excisional biopsy or multiple punch biopsies of the edge are recommended. These measures are taken to rule out malignant tumor, vasculitis, and other rare causes of ulceration.

Additional investigations

In patients with venous insufficiency, a duplex ultrasound scan is helpful to confirm the site and extent of venous reflux. When disease is limited to superficial veins, recurrence may be prevented by stripping the affected veins (3).

In patients with significant edema, arterial pulses may not

be palpable. However, a hand-held Doppler flowmeter can be used to measure the ankle-brachial pressure index, which is the ratio of systolic pressure in the ankle to that in the arm when the patient is in the supine position. Patients with a ratio of 0.7 or less usually have moderate to severe arterial disease, and a vascular surgeon should be consulted for consideration of arterial reconstruction in these patients. In diabetic patients with inelastic vessels, the ankle-brachial pressure index is not helpful; arteriography should be performed instead.

In patients with neuropathy, nylon monofilament can be used to administer a simple test of sensory loss. The end of the monofilament is touched against the bottom of the foot and moved toward the foot until the monofilament buckles, thus ensuring that a known and consistent force has been applied. Patients who cannot feel a pricking sensation from the monofilament have increased risk of neuropathic foot injury.

In some patients with leg ulcers, an x-ray film to rule out osteomyelitis may be appropriate. A positive result warrants orthopedic consultation. Patients with chronic leg ulcers have increased susceptibility to allergic contact dermatitis and should undergo patch testing when the condition is suspected. Commonly seen offending allergens include neomycin, bacitracin, lanolin, and parabens.

Treatment measures according to ulcer type

For complete management of leg ulcers, a holistic approach is necessary. Thus, patients' general health should be assessed and systemic disorders (eg, cardiac failure, anemia, diabetes) should be controlled as much as possible. Cigarette smoking and excessive alcohol intake, which is often accompanied by poor nutrition, adversely affect healing and should be discouraged.

Venous ulcers

Compression is the cornerstone of therapy for venous ulcers. However, it is important to remember that some patients, particularly the elderly, may have arterial insufficiency as well as venous disease. Therefore, to avoid necrosis or gangrene of the foot, the ankle-brachial pressure index should always be measured before compression bandages are applied.

Ambulatory venous pressure and resulting leg edema can be reduced with bed rest, leg elevation, and use of the following compression devices:

- Elastic support stockings. Use of these stockings at a pressure of 30 to 40 mm Hg is recommended in patients with ulcers caused by venous insufficiency. These stockings can be worn during the day and removed at night and for bathing. Patients with arthritis may have difficulty putting these stockings on and may prefer to use the type that zips up.
- Elastic bandages. A variety of these bandages are available, and many are reusable. Correct application is essential for effective compression. Some self-adherent (eg, Coban) wraps are available and help ensure uniform compression over several days.

- Nonelastic bandages. Unna's boots (figure 3: not shown) (eg, DomePaste, UnnaFlex) are gauze bandages impregnated with zinc oxide paste to create a semirigid "boot" when applied. They protect ulcers from the environment and help control edema and are especially helpful in elderly or noncompliant patients because they can be left in place for 7 to 10 days. However, when ulcers produce a large amount of exudate, the boot should be changed more often.
- Multilayer bandages. Several prepackaged systems of three or four bandage layers are available (eg, Dynaflex, Profore), typically consisting of padding to absorb exudate, crepe, and elastic or self-adherent wrap to hold all layers in place. These bandages achieve uniform, sustained compression and can be left in place for a week.
- Pneumatic compression pumps. Use of an intermittent-compression pump should be considered when a venous ulcer does not respond to treatment with standard compression dressings.

Arterial ulcers

Management of arterial ulcers requires surgical reestablishment of an adequate vascular supply whenever possible. Diabetes and cigarette smoking are major risk factors for arterial ulcers, so patients who smoke should be encouraged to stop, and diabetes or other systemic disease (eg, hypertension) should be controlled. Moderate exercise may promote development of collateral circulation, and elevation of the head of the bed 4 to 6 inches improves gravity-dependent arterial flow. Limbs should be kept warm, but direct contact with heat should be avoided because of the risk of thermal injury. Patients should be given detailed instructions about foot care (see box below).

Neuropathic ulcers

In patients with neuropathic ulcers, adequate foot care and daily foot inspection are important, and in those with diabetes, careful control of the disease should be added to the list of preventive-care measures. Ulcers should be extensively debrided and probed to determine the extent and depth of tissue damage. If the wound can be probed to bone, osteomyelitis is likely to be present. To achieve healing in neuropathic foot ulcers, discontinuation of weight bearing is crucial. It can be accomplished through complete bed rest, use of appropriate orthotic footwear, or construction of a non-weight-bearing cast.

Local treatment measures

With the exception of ischemic ulcers, in which debridement of a dry eschar is not usually recommended, all ulcers should be debrided of necrotic and fibrinous debris to allow formation of good granulation tissue and adequate epithelialization. Surgical debridement may be performed in the office using local anesthesia or in the operating room using general anesthesia. Debridement can also be achieved using a variety of dressings. Wet-to-dry saline dressings have been used for many years for wound debridement, but they can be painful and can strip away newly formed epithelium when used on clean wounds.

Less painful debridement can be accomplished with occlusive dressings that provide a moist environment. In acute

wounds, these dressings can lead to rapid epithelialization and lower rates of infection. In chronic wounds, the effect of occlusive dressings is less dramatic, but they achieve painless wound debridement and can be left in place for several days at a time (making them relatively cost-effective). Five basic types of occlusive dressings are available, each with its own advantages and disadvantages (table 4). The choice of dressing is usually determined according to the type of wound, the amount of exudate, cost considerations, and patient and physician preference.

Table 4. Types and characteristics of occlusive wound dressings used for leg ulcers

Type (examples)	Advantages	Disadvantages	Indications
Hydrogels (eg, IntraSite Gel, Nu-gel, Vigilon)	Semitransparent, soothing, do not adhere to wounds, absorbent	Require secondary dressing and frequent dressing changes, expensive	Painful, laser, and partial-thickness wounds; after dermabrasion or chemical peel
Alginates (eg, Algiderm, Kaltostat, Sorbsan)	Absorbent, hemostatic, do not adhere to wounds, fewer dressing changes	Require secondary dressing, gel has foul smell	Highly exudative wounds, partial- or full-thickness wounds; after surgery
Hydrocolloids (eg, Comfeel, DuoDerm, Restore)	Fibrinolytic, enhance angiogenesis, absorbent, create bacterial and physical barrier	Opaque, gel has foul smell, expensive	Partial- or full-thickness wounds, stage 1-4 pressure ulcers
Foams (eg, Allevyn, Curafoam, Lyofoam)	Absorbent, conform to body contours	Opaque, require secondary dressing, may adhere to wounds, expensive	Partial-thickness exudative wounds, for pressure relief
Films (eg, OpSite, Polyskin 11, Tegaderm)	Transparent, create bacterial barrier, adhesive without secondary dressing	May adhere to wounds, can cause fluid collection	Donor sites, superficial burns, partial-thickness wounds with minimal exudate

Systemic treatment measures

Systemic antibiotics should be used only in the presence of cellulitis or systemic infection, with the choice of agents guided by bacterial culture and sensitivity results. The anabolic steroid stanozolol (Winstrol) has been reported to be effective in treating acute lipodermatosclerosis and ulcers caused by cryofibrinogenemia, but it has no effect on established ulcers. Pentoxifylline (Trental) (400 mg three times daily) may be helpful in treatment of peripheral arterial and venous disease.

Skin grafting

Skin grafts are often helpful in promoting healing of leg ulcers, because even if they do not take, grafts seem to stimulate wound epithelialization. For large wounds, split-thickness skin grafting can be performed using local, spinal, or general anesthesia. Meshed grafts are useful for large ulcers, because they allow exudate to escape through the graft interstices. However, the donor site may be painful and slow to heal, especially in elderly patients.

For smaller wounds, pinch grafting is a useful option. Multiple small pinches (or, alternatively, superficial punch biopsies) are taken from a donor site (eg, thigh) and placed dermal side down on the ulcer bed.

New treatments for chronic ulcers

The US Food and Drug Administration has approved topical recombinant human platelet-derived growth factor (becaplermin [Regranex]) for adjunctive treatment of lower extremity diabetic ulcers. Typically, the agent, which is formulated into a gel, is used along with initial surgical debridement, pressure relief, and infection control. The gel is applied to the ulcer once daily, covered by a saline-moistened dressing, and left in place for about 12 hours. Then, the dressing is removed, residual gel is rinsed away with saline or water, and the ulcer is re-covered with a moist dressing for the remainder of the 24-hr period.

Once-daily application of the gel to the ulcer is indicated until healing is complete or 20 weeks have passed, at which time treatment should be reassessed. In an initial randomized controlled trial (4,5), recombinant platelet-derived growth factor significantly improved healing of diabetic foot ulcers compared with placebo. Generally, however, a lower rate of healing of chronic diabetic foot ulcers was found in medical centers where debridement was performed less often, which emphasizes the vital role of wound debridement.

In a large multicenter study, a human skin equivalent (Apligraf) was used to treat chronic venous ulcers (6), and it appeared to be particularly helpful in long-standing deep ulcers. Complete wound closure was achieved more often and more quickly in patients treated with the skin substitute than in those receiving standard compression therapy. This effect was statistically significant only in patients with ulcers of more than 6 months' duration. Nonetheless, use of bioengineered skin grafts may be helpful in patients with large, chronic venous ulcers.

Summary

The cause of a leg ulcer should be determined before a course of treatment is undertaken, and this often can be accomplished through history taking, physical examination, and use of simple noninvasive testing. Most leg ulcers are caused by venous disease, arterial insufficiency, neuropathy, or a combination of these factors.

Complete management should address the patient's general health as well as specific findings, and treatment of any underlying cause is paramount. In venous ulcers, compression is the cornerstone of treatment, and a variety of effective stockings and other compression devices are available. Arterial ulcers usually require reestablishment of an adequate vascular supply, often through surgery. Neuropathic ulcers need thorough debridement to allow good granulation and epithelialization. Five types of occlusive dressings are available that achieve debridement less painfully but also more slowly than the surgical approach. Several adjunctive methods are now available that facilitate successful therapy in these ulcers, which have often been considered nonhealing wounds.

References

1. **Phillips TJ, Dover JS.** Leg ulcers. *J Am Acad Dermatol* 1991;25(6 Pt 1):965-87
2. **Caputo GM, Cavanagh PR, Ulbrecht JS, et al.** Assessment and management of foot disease in patients with diabetes. *N Engl J Med* 1994;331(13):854-60
3. **Darke SG, Penfold C.** Venous ulceration and saphenous ligation. *Eur J Vasc Surg* 1992;6(1):4-9
4. **Steed DL, Donohoe D, Webster MW, et al, for the Diabetic Ulcer Study Group.** Effect of extensive debridement and treatment on the healing of diabetic foot ulcers. *J Am Coll Surg* 1996;183(1):61-4
5. **Wieman TJ, Smiell JM, Su Y.** Efficacy and safety of a topical gel formulation of recombinant human platelet-derived growth factor-BB (becaplermin) in patients with chronic neuropathic diabetic ulcers: a phase III randomized placebo-controlled double-blind study. *Diabetes Care* 1998;21(5):822-7
6. **Falanga V, Margolis D, Alvarez O, et al, for the Human Skin Equivalent Investigators Group.** Rapid healing of venous ulcers and lack of clinical rejection with an allogeneic cultured human skin equivalent. *Arch Dermatol* 1998;134(3):293-300

INFORMATION FOR PATIENTS

Tips for avoiding foot problems--especially important if you have diabetes or a nerve disorder
 Stop smoking.
 Inspect your feet daily for blisters, scratches, and red areas.
 If you don't see well, have someone do this for you.
 Wash your feet daily in warm water. Dry carefully and completely between your toes.
 Always test the water temperature before bathing. Make sure it's warm but not hot.

Put petroleum jelly on dry areas on your feet, but not between your toes.
Never walk barefoot.
Wear shoes that fit right and feel good.
Make sure there are no rough and worn areas, ridges, or stones inside your shoes before you put them on.
Wear new shoes for only an hour or two a day at first. When you take off new shoes, check your feet for red spots.
Inform your doctor if any breaks in the skin or blisters develop on your feet.
Do not wear open-toed or pointed shoes.
Do not remove corns or apply strong chemicals to your feet.
Cut your toenails straight across.
See your podiatrist regularly.
See your doctor regularly.

Adapted, with permission, from Phillips and Dover (1).

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